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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/654,281	09/01/2000	John M. Sedivy Ph.D.	3564/1010	5838

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EXAMINER

RAWLINGS, STEPHEN L

ART UNIT PAPER NUMBER

1642

DATE MAILED: 03/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/654,281

Applicant(s)

SEDIVY PH.D. ET AL.

Examiner

Stephen L. Rawlings, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-45 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Election Facsimile Cover Sheet*.

DETAILED ACTION

1. Claims 1-45 are pending in the application and are currently subject to restriction.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - Group I. Claims 1-20, drawn to a method for identifying an agent, said method comprising contacting a polypeptide with an agent and monitoring binding of the agent to the polypeptide, classified in class 435, subclass 4.
 - Group II. Claims 21 and 22, drawn to a method for identifying an agent, said method comprising contacting a polypeptide with its binding partner in the presence of an agent and monitoring the association of the polypeptide and its binding partner, classified in class 435, subclass 4.
 - Group III. Claims 23-25, drawn to a method for identifying an agent, said method comprising measuring reporter gene expression in the presence of an agent, classified in class 435, subclass 4.
 - Group IV. Claims 26 and 27, drawn to a method for detecting a condition, said method comprising measuring and comparing amounts of RNA, classified in class 435, subclass 6.
 - Group V. Claims 28-30, drawn to a method for detecting a condition, said method comprising measuring and comparing amounts of protein, classified in class 435, subclass 7.1.
 - Group VI. Claim 31, drawn to a method for identifying an agent, said method comprising detecting phosphorylation of a polypeptide in the presence of an agent, classified in class 435, subclass 4.
 - Group VII. Claims 33-37, drawn to a method for inhibiting the activity of a kinase, said method comprising contacting a kinase with an agent, classified in class 435, subclass 194.
 - Group VIII. Claims 38 and 39, drawn to a method for treating, said method comprising administering a composition comprising an agent to an

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individual, which cannot be classified since the nature of the agent is not disclosed.

Group IX. Claims 40-42, drawn to a polypeptide, classified in class 530, subclass 350.

Group X. Claims 43-45, drawn to a nucleic acid, classified in class 536, subclass 23.5.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions in groups IX and X are disclosed as biologically and chemically distinct, unrelated in structure and/or function, and/or made by and/or used in different methods and therefore, the claimed products are distinct.

Inventions in groups I-VIII are disclosed as materially different methods that differ at least in objectives, method steps, reagents and/or doses and/or schedules used, response variables, assays for end products and/or results, and criteria for success and therefore, the claimed methods are distinct.

Inventions in group IX and groups I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product, such as producing antibodies that specifically bind to the polypeptide.

The inventions in group X and groups I-VIII are not at all related because the products of group X are not specifically used in any of the steps of the claimed methods in groups I-VIII.

The inventions in group IX and groups III-VIII are not at all related because the products of group IX are not specifically used in any of the steps of the claimed methods in groups III-VIII.

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4. Because these inventions are distinct for the reasons given above and also because the search required for any one group is not required for any other group and/or the inventions have acquired a separate status in the art as shown by their different classification or their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. The generic claims are also subject to an election of species requirement:

(A) Claims 1, 5, 11, and 16 within group I are generic to a plurality of disclosed patentably distinct species comprising a method for identifying an agent comprising detecting binding by (a) surface plasmon resonance, (b) yeast two-hybrid system, (c) pull-down assay, (d) FRET, (e) fluorescence polarization assay, (f) scintillation proximity assay, (g) transcription assay, (h) kinase assay, or (i) transformation assay, according to claims 2, 6, 12, and 17, respectively. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

(B) Claim 21 within group II is generic to a plurality of disclosed patentably distinct species comprising a method for identifying an agent comprising monitoring by (a) surface plasmon resonance, (b) yeast two-hybrid system, (c) pull-down assay, (d) FRET, (e) fluorescence polarization assay, or (f) scintillation proximity assay, according to claim 22. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

(C) Claim 23 in group III is generic to a plurality of disclosed patentably distinct species comprising a method for identifying an agent comprising providing a cell comprising a reporter gene construct wherein the expression of the reporter gene is controlled by (a) an AP-1 sensitive control region or (b) an NF- κ B sensitive control region, according to claims 24 and 25, respectively. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

(D) Claim 26 in group IV is generic to a plurality of disclosed patentably distinct species comprising a method for detecting a condition comprising measuring

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RNA by (a) RT-PCR, (b) RNase protection assay, (c) *in situ* hybridization, or (d) Northern hybridization, according to claim 27. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

(E) Claim 31 in group VI is generic to a plurality of disclosed patentably distinct species comprising a method for identifying an agent comprising providing a system that permits phosphorylation of (a) Raf, (b) MEK, (c) ERK, (d) NIK, or (e) TAK, according to claim 32. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

6. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is

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(703) 305-3008. The examiner can normally be reached on Monday-Thursday, alternate Fridays, 8:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.

Examiner

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DOUG WORTMAN
PATENT EXAMINER

slr

March 1, 2002



RESTRICTION ELECTION FACSIMILE TRANSMISSION

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